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10/519,888	12/29/2004	Claude Moirandat	93544	2577

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EXAMINER

EDWARDS, LYDIA E

ART UNIT	PAPER NUMBER
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1709

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,888

Applicant(s)

MOIRANDAT ET AL.

Examiner

Lydia Edwards

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-14 is/are rejected.
- 7) ☒ Claim(s) 4-6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/29/2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/8/2005.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: references to the claims are made on page 3.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7-12 and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by JP 2002-360672.

JP 2002-360672 discloses a method for decontaminating a processing container (clean-room) in which the clean-room is supplied with gaseous H_2O_2 and H_2O_2 still present in the clean-room is chemically broken down without catalyst at a later time point by supplying at least one gaseous agent which reacts with the H_2O_2 , wherein the gaseous agent comprises ozone [0006]-[0022].

Regarding Claim 2, H_2O_2 residues in a product situated in the clean room is subsequently broken down on the product in a targeted manner by control of ozone level.

Regarding Claim 3, a gaseous agent (ozone) is metered in such a manner that after the chemical breakdown of the H_2O_2 at most 1 ppm of H_2O_2 still remains in the clean-room [0022].

Regarding Claim 7, the gaseous agent comprises ozone.

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Regarding Claim 8, JP 2002-36072 discloses a system for decontaminating a clean room having an H_2O_2 supply device for supplying the clean-room with H_2O_2 , comprising H_2O_2 breakdown device for effecting a chemical breakdown of H_2O_2 without catalyst in the clean-room which further comprises means for introducing at least one gaseous agent into the clean-room.

Regarding Claim 9, the means for introducing is constructed to introduce ozone.

Regarding Claim 10, the means for introducing at least one gaseous agent into the clean-room has a generator for generating gaseous agent, a gas line from the generator to the clean-room and a valve for regulating the amount of the gaseous agent flowing through the gas line.

Regarding Claim 11, the system further includes a sensor measuring the concentration of the gaseous agent in the clean-room the measured values of which serve to control the breakdown device [0117].

Regarding Claim 12, the system further includes a sensor for measuring the H_2O_2 concentration in the clean-room, the measured values of which serve to control the H_2O_2 breakdown device [0009].

Regarding Claim 14, the H_2O_2 breakdown device and the H_2O_2 supply device are integrated into a periphery of the clean-room.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

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Claims 1-3, 8-10 and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by EP 0 456 135.

EP 0 456 135 discloses a method for decontaminating a sterilizing chamber (clean-room) in which the clean-room is supplied with gaseous H_2O_2 and H_2O_2 still present in the clean-room is chemically broken down without catalyst at a later time point by supplying at least one gaseous agent which reacts with the H_2O_2 , wherein the gaseous agent comprises plasma made from gas mixtures containing argon, helium, nitrogen oxygen, hydrogen or mixtures thereof (Columns 3-6).

Regarding Claim 2, H_2O_2 residues in a product situated in the clean room is subsequently broken down on the product in a targeted manner by control of ozone level.

Regarding Claim 3, the gaseous agent (plasma gas) is metered in such a manner that after the chemical breakdown of the H_2O_2 at most 1 ppm of H_2O_2 still remains in the clean-room (hydrogen peroxide residues entirely eliminated (Col. 5, lines 53-55)).

Regarding Claim 8, EP 0 456 135 discloses a system for decontaminating a clean room having an H_2O_2 supply device for supplying the clean-room with H_2O_2 , comprising H_2O_2 breakdown device for effecting a chemical breakdown of H_2O_2 without catalyst in the clean-room which further comprises means for introducing at least one gaseous agent into the clean-room (Col. 8, lines 11 – Col. 10, line 41).

Regarding Claim 9, the means for introducing is constructed to introduce ammonia, hydrazine or ozone (the delivering tubes capable of introducing ammonia, hydrazine or ozone - (Col. 8, lines 11-30)).

Regarding Claim 10, the means for introducing at least one gaseous agent into the clean-room has a supply vessel filled with gaseous agent, a gas line from the supply vessel to the clean-room and a valve for regulating the amount of the gaseous agent flowing through the gas line.

Regarding Claim 14, the H₂O₂ breakdown device and the H₂O₂ supply device are integrated into a periphery of the clean-room (Fig. 1).

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (US 5820841).

Regarding Claim 1, Chen et al. ('841) discloses a method for decontaminating a clean-room in which the clean-room is supplied with gaseous H₂O₂ and H₂O₂ still present in the clean-room is chemically broken down without catalyst at a later time point by supplying at least one gaseous agent which reacts with the H₂O₂ (Col 8, lines 62-64, Col 9, lines 1-7 and 21-27).

Regarding Claim 2, Chen et al. ('841) discloses that wherein H₂O₂ residues in a product situated in the clean room is subsequently broken down on the product in a targeted manner (Col 8, lines 62-64, Col 9, lines 21-27).

Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (US 5820841) and Protic et al. (WO02/07788).

Regarding Claim 8, Chen et al. ('841) discloses a system for decontaminating a clean room having an H₂O₂ supply device for supplying the clean-room with H₂O₂, comprising H₂O₂ breakdown device for effecting a chemical breakdown of H₂O₂ without catalyst in the clean-room which further comprises means for introducing at least one gaseous agent into the clean-room (Col 8, lines 62-64, Col 9, lines 1-7 and 21-27).

Protic et al. ('788) also discloses a system for decontaminating a clean room having an H₂O₂ supply device for supplying the clean-room with H₂O₂, comprising H₂O₂ breakdown device for effecting a chemical breakdown of H₂O₂ without catalyst in the clean-room which

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further comprises means for introducing at least one gaseous agent into the clean-room (page 3 and 27)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 5820841) as applied to claim 1 above, and further in view of Childers et al. (US 5837193).

Chen et al. does not specifically teach an effectiveness standard of 1 ppm of H₂O₂ that still remains in the clean room.

Regarding Claim 3, Childers et al. (US '193) discloses that a gaseous agent is metered in such a manner that after the chemical breakdown of the H₂O₂ at most 1 ppm of H₂O₂ still remains in the clean-room (Col 10, lines 50-53).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Chen et al. with the effectiveness standard as taught by Childers et al. in order to comply with the international sterility assurance limit.

Claims 7, 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 5820841) as applied to claim 1 above, and further in view of Protic et al. (WO02/07788).

Regarding Claim 7, Chen et al. ('841) does not teach the use of ozone as a gaseous agent.

Protic et al. ('788) disclose the use of ozone as a gaseous agent (page 3 and 10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Chen et al. with the use of ozone as taught by Protic et al., to further breakdown and remove the H₂O₂ residual remaining on the item(s) to be sterilized. The use of ozone to breakdown and remove residuals of gaseous sterilants is well known in the art.

Regarding Claim 9, Protic et al. ('788) discloses a means for introducing ozone into the clean-room (page 28)

Regarding Claim 10, Protic et al. ('788) discloses means for introducing at least one gaseous agent into the clean-room has a supply vessel filled with gaseous agent, or a generator for generating gaseous agent, a gas line from the supply vessel or generator to the clean-room and a valve for regulating the amount of the gaseous agent flowing through the gas line (page 28).

Although Protic et al. does not specifically mention the use of a valve, they are however depicted in figure 7 (1-5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to know that a valve is necessary when using a generator to supply a predetermined amount of a gaseous agent to a clean room. Furthermore the system has

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to be regulated given that sterilant/sterilization is commonly applied in multiple doses. Hence, it would have been of obvious matter of design choice to include a valve for regulating the amount of the gaseous agent flowing through the gas line.

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Protic et al. (WO02/07788) as applied to claim 8 above, and in further view of Platt Jr. et al. (US 6458321).

Protic et al. does not teach a means of sensing and controlling the concentration of the gaseous agent.

Regarding Claim 11, Platt Jr. et al. ('321) discloses a means for measuring the concentration of the gaseous agent in the clean-room the measured values of which serve to control the breakdown device (Col 5, lines 61-67 and Col 6, lines 1-18).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Protic et al. with a means of sensing and controlling the concentration as taught by Platt Jr. et al. in order to better control the amount of gaseous agent that needs to be released to effectively remove the sterilant residual in accordance with the international sterility assurance limit.

Regarding Claim 12, Platt Jr. et al. ('321) discloses a means for measuring the H2O2 concentration in the clean-room the measured values of which serve to control the H2O2 breakdown device (Col 3, lines 60-67 and Col 4, lines 1-6).

Protic et al. does not teach a means of sensing and controlling the concentration of H2O2).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Protic et al. with a means of sensing and controlling the concentration as taught by Platt Jr. et al. in order to better control the amount of sterilant that is released to as such to eliminate excess residual.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Protic et al. (WO02/07788) as applied to claim 8 above, and in further view of Caputo et al. (US 5645796).

Protic et al. does not teach a UV light.

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Regarding Claim 13, Caputo et al. ('796) discloses an H₂O₂ breakdown device that has means for generating UV light in the clean-room (Col 8, lines 16-21 and lines 47-52)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Protic et al. with a means for generating UV light as taught by Caputo et al. in order to provide an additional means to ensure the removal of residual sterilant.

Regarding Claim 14, Protic et al. ('788) discloses that the H₂O₂ breakdown device H₂O₂ supply device are integrated into a periphery of the clean-room (page 27-28).

Allowable Subject Matter

Claims 4-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding Claim 4, prior art does not teach that ammonia used as a gaseous agent.

Regarding Claim 5, prior art does not teach that ammonia is metered as a function of the H₂O₂ in such a manner that the excess of ammonia is at most 500 ppm.

Regarding Claim 6, prior art does not teach that hydrazine is used as a gaseous agent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lydia Edwards whose telephone number is (571) 270-3242. The examiner can normally be reached on Mon-Fri 8-5 (Alternate Fri).

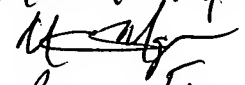
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lydia Edwards
Examiner
Art Unit 1709

LE

Melvin Mayes

Primary Examiner
AU1734